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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,182	07/25/2001	Katayoon Dehesh	MTC 6796	5251

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EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	//

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/915,182	DEHESH, KATAYOON	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become* ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *22-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ *Information Disclosure Statement(s)* (PTO-1449) Paper No(s) *4,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II are not distinct. This is not found persuasive because the DNA of Group I can be used in a method other than that of Group II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 32, a dependent claim should refer to a preceding claim and not a claim yet to be recited. It appears from the structure of Claims 31-36 that Applicant intended to recite "Claim 31" instead of "Claim 35" in line 1 of Claim 32.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-21, and 31-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated polynucleotide encoding a polypeptide having KAS activity consisting of a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and a sequence complementary thereof; a polynucleotide comprising SEQ ID NO: 1 and a sequence complementary thereof; a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 and a sequence complementary thereof; a polynucleotide with at least 70-95% sequence identity over the entire length SEQ ID NO: 1 and a sequence complementary thereof; or a polynucleotide of the formula X-(R1)n-(R2)-(R3)n-Y wherein R1 and R2 are any nucleotide residue, R3 is SEQ ID NO: 1, X is a 5' end hydrogen, and Y is 3' end hydrogen or metal; and a nucleic acid construct comprising a polynucleotide encoding a delta-9 desaturase enzyme.

Applicant describes a polynucleotide of SEQ ID NO: 1 from *Synechocystis* encoding a polypeptide of SEQ ID NO: 2; seed specific expression cassettes for *Brassica* transformation (pCGN8378) and soy transformation (pCGN9807) comprising polynucleotides from *C. Pullcherrimma* encoding KASI and KASIV (WO 98/46776); and seed specific expression cassettes (pCGN3231 from U.S. Patent 5,723,595) for *Brassica* transformation and (pCGN9883) for soy transformation comprising the safflower delta-9 desaturase gene (G. Thompson *et al.*, PNAS, Vol. 88, pp. 2578-2582).

Applicant does not describe any isolated polynucleotides encoding a KAS activity other than SEQ ID NO: 1 from *Synechocystis* encoding a polypeptide of SEQ ID NO: 2; the genes for KASI and KASIV from *C. pullcherrimma* (WO 98/46776); and the safflower delta-9 desaturase (Thompson *et al.* PNAS Vol. 8 pp. 2578-2582)

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.,* 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Given the failure of the DNA encoding a polypeptide having a KAS activity to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

Claims 1, 3-21, and 31-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an isolated polynucleotide encoding a polypeptide having KAS activity consisting of a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and a sequence

complementary thereof; a polynucleotide comprising SEQ ID NO: 1 and a sequence complementary thereof; a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 and a sequence complementary thereof; a polynucleotide with at least 70-95% sequence identity over the entire length SEQ ID NO: 1 and a sequence complementary thereof; or a polynucleotide of the formula X-(R1)n-(R2)-(R3)n-Y wherein R1 and R2 are any nucleotide residue, R3 is SEQ ID NO: 1, X is a 5' end hydrogen, and Y is 3' end hydrogen or metal; a nucleic acid construct comprising a polynucleotide encoding a delta-9 desaturase enzyme; and plants transformed with an expression cassette expressing a beta-ketoacyl-ACP synthase isoalted from *Synechocystis* (Syn FabF) having less than about 3.5% weight percent saturated fatty acid.

Applicant teaches isolation of a polynucleotide of SEQ ID NO: 1 from *Synechocystis* encoding a polypeptide of SEQ ID NO: 2; transformed *Brassica* having less than about 3.5% weight percent saturated fatty acid in plants co-expressing beta-ketoacyl-ACP synthase genes from *C. Pullcherrimma* encoding KASI and KASIV (WO 98/46776) and the safflower delta-9 desaturase gene (G. Thompson *et al.*, PNAS, Vol. 88, pp. 2578-2582); and transformed soybean having less than about 3.5% weight percent saturated fatty acid in plants expressing a beta-ketoacyl-ACP synthase from *C. Pullcherrimma* encoding KASI and KASIV (WO 98/46776) and the safflower delta-9 desaturase gene (G. Thompson *et al.*, PNAS, Vol. 88, pp. 2578-2582).

Applicant does not teach any other polynucleotide encoding a beta-ketoacyl-ACP synthase isolated from any other source other than the beta-ketoacyl-ACP synthase gene from *Synechocystis* and the genes from *C. Pullcherrimma* encoding KASI and KASIV; and plants

transformed with an expression cassette expressing a beta-ketoacyl-ACP synthase isolated from *Synechocystis* (Syn FabF) having less than about 3.5% weight percent saturated fatty acid.

Isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

Further, the isolation of orthologous DNA sequences from other species introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable either PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited homology. Thus the screen for orthologous sequences would isolate many genes other than those of interest. The inherent unpredictability in isolation of a homologous sequence encoding the same protein activity is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a

range of enzymes involved in fatty acid metabolism (Broun *et al.* Science Vol. 282, 13 November 1998; Abstract lines 4-6 and p. 1317 column 1, lines 51-56).

Applicant has based their claim to reduced levels of saturated fatty acids of less than about 3.5% in the non-exemplified seeds from non-exemplified plants transformed with the non-homologous nucleic acid sequence of SEQ ID NO: 1 from *Synechocystis* upon results that showed levels of saturated oils in seeds of soybean plants transformed with both KASI and KAS IV (both encoding beta-ketoacyl-ACP synthases) from the plant *C. pulcherrima* covering a range from 2.5% up to the 13% found in wild type soybean seeds. Similar achievement of reduced saturated fatty acid insoybean seeds using KAS-II from *Synechocystis* would require undue experimentation for one skilled in the art.

Further, the expression of antisense beta-ketoacyl-ACP synthase is not enabling for the reduction of saturated fatty acids in general, due to the nature of fatty acid synthesis (FAS); and that the coordinate regulation of enzymes involved in FAS may act to counter disruption of homeostasis in fatty acid biosynthesis (Dehesh K. *et al.,* Plant Physiology, February 2001, Vol. 125, pp. 1103-1114; on page 1104 column 1, lines 24-37 and page 1110 column 1, lines 31-55). Applicant is invited to submit a Rule 132 Declaration containing data on the fatty acid levels in the seeds of plants transformed with SEQ ID NO: 1.

Given the lack of guidance for isolating any other beta-ketoacyl-ACP synthase gene, or for producing plants transformed with varied sequence identities to SEQ ID NO: 1 encoding a beta-ketoacyl-ACP synthase from *Synechocystis* in sense or antisense orientation or any other non-exemplified genes encoding a beta-ketoacyl-ACP synthase, the breadth of the claims, and given the unpredictability in the art, undue trail and error experimentation would be needed by

one skilled in the art to isolate a multitude of non-exemplified beta-ketoacyl-ACP synthase genes, or to evaluate the ability of a multitude of non-exemplified beta-ketoacyl-ACP synthase genes or non-exemplified gene fragments to alter the phenotype of a multitude of transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8, 10-21, 31, 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claims 2-8, "An isolated polynucleotide" is indefinite. Claims 2-8 depend from Claim 1 that recites "an isolated polynucleotide selected from the group". This limitation of Claim 1 indicates that there is one distinct polynucleotide claimed. Claims 2-8 should read --The isolated polynucleotide--.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9 and 17-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed plants and seeds, which are a product of nature and not one of the five classes of patentable subject matter.

The DNA of Claim 9, since it has not been isolated by the hand of man reads as a product of nature, thus falling outside the five classes of patentable subject matter. The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter.

Claims 17-21 are drawn to parts such as seeds and progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature.

See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko T. *et al.*, GenBank Accession number S77464 submitted June 1996 from Kaneko T. *et al.*, DNA Research, Vol. 3, pp. 109-136, June 19, 1996.

Kaneko teaches the protein sequence of SEQ ID NO: 2 of a beta-ketoacyl-ACP synthase II from *Synechocystis* that inherently teaches the polynucleotide coding sequence of SEQ ID NO: 1 encoding said protein. Thus, the cited reference teaches all the limitations of Claims 1-8.

Claims 1, 7-8, 10-11, 14-16, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferri S. *et al.*, WO98/32770 PCT publication date July 30, 1998.

Claims are broadly drawn as discussed supra, specifically an isolated nucleotide that hybridizes to SEQ ID NO: 1 under hybridization and wash conditions of unspecified temperature, stringency, and duration.

Ferri teaches an isolated nucleotide sequence from a cyanobacterium (*Anacystis nidulans*) that would hybridize to SEQ ID NO: 1 encoding a beta-ketoacyl-ACP synthase II enzyme and a nucleic acid construct comprising a promoter functional in a host cell operably linked to the KAS-II synthase gene from *Anacystis nidulans* in sense orientation for increasing the amount of unsaturated fatty acids in plants (Column 6 lines 1-13, Column 8 Example 3, and Column 24 lines 9-10).

Claims 1, 7-8, 10-21, and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Knauf V. *et al.*, U.S. Patent 5,510,255 published April 23, 1996.

Knauf teaches the use of an isolated nucleotide encoding a beta-ketoacyl-ACP synthase II or isolated nucleotides encoding both a beta-ketoacyl-ACP synthase II and a delta-9 desaturase together in a vector or in separate vectors for the production of fatty acids having little or no completely saturated chains in the seeds of either corn, rapeseed, or soybean (Abstract lines 1-3, Column 8 lines 47-52, Column 52 lines 56-67, and Column 99 lines 51-54). Thus, the reference teaches all of the limitations of Claims 1, 7-8, 10-21 and 31-36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-21, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knauf *et al.* U.S. Patent 5,510,255 published April 23, 1996 in view of Kaneko T. *et al.*, DNA Research, Vol. 3, pp. 109-136, June 19, 1996.

Applicant claims an isolated polynucleotide encoding a polypeptide having KAS activity consisting of a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and a sequence complementary thereof; a polynucleotide comprising SEQ ID NO: 1 and a sequence complementary thereof; a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 and a sequence complementary thereof; a polynucleotide with at least 70-95% sequence identity over the entire length SEQ ID NO: 1 and a sequence complementary thereof; or a polynucleotide of the formula X-(R1)n-(R2)-(R3)n-Y wherein R1 and R2 are any nucleotide residue, R3 is SEQ ID NO: 1, X is a 5' end hydrogen, and Y is 3' end hydrogen or metal; a nucleic acid construct comprising a polynucleotide encoding a delta-9 desaturase enzyme; and plants transformed with an expression cassette expressing a beta-ketoacyl-ACP synthase isolated from *Synechocystis* (Syn FabF) having less than about 3.5% weight percent saturated fatty acid.

The teachings of Knauf are discussed supra.

Knauf does not teach SEQ ID NO: 1 encoding SEQ ID NO: 2.

The teachings of Kaneko are discussed supra.

It would have been obvious at the time of Applicant's invention to modify the invention of Knauf to substitute the beta-ketoacyl-ACP synthase II gene for the one taught by Kaneko. One of ordinary skill in the art would have been motivated by the teachings of Knauf that the plant genes encoding a beta-ketoacyl-ACP synthase and delta-9 desaturase are valuable materials for genetic engineering of plants having little or no completely saturated fatty acid chains in their seeds, and that one would have had a reasonable expectation of success of expressing genes in transformed plants and plant cells.

Claims 1-8, 10-11, 14-16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferri S. *et al.*, WO98/32770 PCT publication date July 30, 1998 in view of Kaneko T. *et al.*, DNA Research, Vol. 3, pp. 109-136, June 19, 1996.

Applicant claims an isolated polynucleotide encoding a polypeptide having KAS activity consisting of a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and a sequence complementary thereof; a polynucleotide comprising SEQ ID NO: 1 and a sequence complementary thereof; a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 and a sequence complementary thereof; a polynucleotide with at least 70-95% sequence identity over the entire length SEQ ID NO: 1 and a sequence complementary thereof; or a polynucleotide of the formula X-(R1)n-(R2)-(R3)n-Y wherein R1 and R2 are any nucleotide residue, R3 is SEQ ID NO: 1, X is a 5' end hydrogen, and Y is 3' end hydrogen or metal; a nucleic acid construct comprising a polynucleotide encoding a delta-9 desaturase enzyme; and plants transformed with an expression cassette expressing a beta-

ketoacyl-ACP synthase isoalted from *Synechocystis* (Syn FabF) having less than about 3.5% weight percent saturated fatty acid.

The teachings of Ferri are discussed supra

Ferri does not teach SEQ ID NO: 1 encoding SEQ ID NO: 2.

The teachings of Kaneko are discussed supra.

It would have been obvious at the time of Applicant's invention to modify the invention of Ferri to substitute the beta-ketoacyl-ACP synthase II gene for the one taught by Kaneko. One of ordinary skill in the art would have been motivated by the teachings of Ferri that the plant genes encoding a beta-ketoacyl-ACP synthase and delta-9 desaturase are valuable materials for genetic engineering of plants having little or no completely saturated fatty acid chains in their seeds, and that one would have had a reasonable expectation of success of expressing genes in transformed plants and plant cells.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Russell Kallis Ph.D.
December 21, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~100~~ 1638